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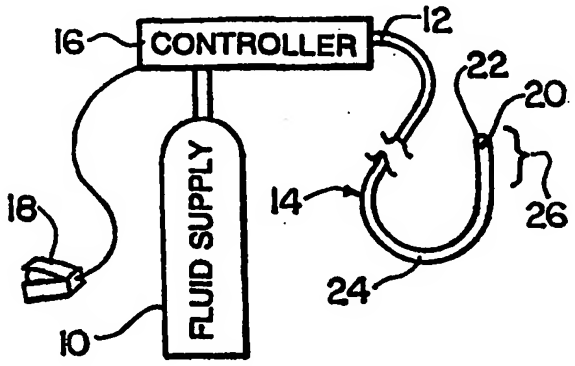
(57) Abstract

A cryogenic catheter (14) includes a flexible member (24) having an elongate, thermally transmissive region (26), and a cryogenic fluid path through the flexible member to the thermally transmissive region. The thermally transmissive region can be deformable from a linear configuration to an arcuate configuration, and can include multiple thermally transmissive elements ((34) for example) having a first side exposed to the cryogenic fluid path, and a second side exposed to points exterior to the flexible member. The thermally transmissive elements can be rigid or flexible longitudinal strips. Alternatively, annular, cylindrical, or wedge shaped metallic structures disposed in a spaced apart relationship, can define the thermally transmissive region. In other embodiments the thermally transmissive region is defined by a helical coil (52) that is at least partially embedded in the flexible member. The helical coil can also define at least a portion of the cryogenic fluid path through the flexible member, and include a gas expansion or boiling chamber (68).



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METHOD AND APPARATUS FOR LINEAR ABLATION

FIELD OF THE INVENTION

The invention relates to catheters, and more particularly to cryosurgical catheters used for tissue ablation.

BACKGROUND OF THE INVENTION

Many medical procedures are performed using minimally invasive surgical techniques, wherein one or more slender implements are inserted through one or more small incisions into a patient's body. With respect to ablation, the surgical implement can include a rigid or flexible structure having an ablation device at or near its distal end that is placed adjacent to the tissue to be ablated. Radio frequency energy, microwave energy, laser energy, extreme heat, and extreme cold can be provided by the ablation device to kill the tissue.

With respect to cardiac procedures, a cardiac arrhythmia can be treated through selective ablation of cardiac tissue to eliminate the source of the arrhythmia. A popular minimally invasive procedure, radio frequency (RF) catheter ablation, includes a preliminary step of conventional electrocardiographic mapping followed by the creation of one or more ablated regions (lesions) in the cardiac tissue using RF energy. Multiple lesions are frequently required because the effectiveness of each of the proposed lesion sites cannot be predetermined due to limitations of conventional electrocardiographic mapping. Often, five lesions, and sometimes as many as twenty lesions may be required before a successful result is attained. Usually only one of the lesions is actually effective; the other lesions result in unnecessarily destroyed cardiac tissue.

Deficiencies of radio frequency ablation devices and techniques have been overcome by using cold to do zero degree or ice mapping prior to creating lesions, as taught in U.S. Patent Nos. 5,423,807; and 5,281,213; and 5,281,215. However, even though combined cryogenic mapping and ablation devices permit greater

certainty and less tissue damage than RF devices and techniques, both the cryogenic and the RF devices are configured for spot or roughly circular tissue ablation.

Spot tissue ablation is acceptable for certain procedures. However, other procedures can be more therapeutically effective if multiple spot lesions along a predetermined line, or a single elongate or linear lesion is created in a single ablative step. Radio frequency ablation devices are known to be able to create linear lesions by dragging the ablation tip along a line while it is active. However, no cryogenic devices are known that are optimized for, or which are even minimally capable of, creating an elongate lesion.

SUMMARY OF THE INVENTION

The present invention provides a cryogenic ablation system including a cryosurgical catheter that is particularly well suited for creating elongate lesions. In an exemplary embodiment, a cryogenic catheter includes a flexible member having an elongate, thermally-transmissive region and a cryogenic fluid path through the flexible member to the thermally-transmissive region. The thermally-transmissive region can be deformable from a linear configuration to an arcuate configuration and can include multiple, thermally-transmissive elements having a first side exposed to the cryogenic fluid path and a second side exposed to points exterior to the flexible member.

The thermally-transmissive elements can be rigid or flexible longitudinal strips. Alternatively, rigid or flexible annular, cylindrical, or wedge-shaped metallic structures disposed in a spaced-apart relationship can define the thermally-transmissive region. The thermally-transmissive elements can define continuous 360 degree structures or arcuate structures that are less than 360 degrees and/or which do not fully traverse the circumference of the catheter.

In other embodiments, the thermally-transmissive region is defined by a helical coil that is at least partially embedded in the flexible member. The helical coil can also define at least a portion of the cryogenic fluid path through the flexible member and can include a gas expansion or boiling chamber.

The cryogenic catheter of the invention can be a component in a cryogenic

system that further includes a cryogenic fluid supply in communication with the cryogenic catheter, and a fluid controller interposed between the cryogenic catheter and the cryogenic fluid supply for regulating the flow of the cryogenic fluid into the cryogenic catheter. The cryogenic fluid can be a gas or a liquid.

The present invention further includes a method of making an elongate lesion, wherein cryogenic temperatures are sequentially achieved along a thermally-transmissive region over a predetermined time interval.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention and the attendant advantages and features thereof will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a schematic illustration of an embodiment of a cryosurgical system in accordance with the invention;

FIG. 2 is a sectional view of a heart muscle showing placement of the catheter of FIG. 1;

FIG. 3 illustrates the tip region of one embodiment of the catheter in accordance with the invention;

FIG. 4 illustrates an alternative embodiment of the catheter of FIG. 3;

FIG. 5 illustrates yet another embodiment of the catheter;

FIG. 6 illustrates a deformable tip for a catheter;

FIG. 7 illustrates yet another embodiment of the catheter;

FIG. 8 is a sectional view of the catheter of FIG. 7 taken along line 8-8;

FIG. 9 is a sectional view of an alternative embodiment of the linear ablation catheter illustrated in FIG. 7;

FIG. 10 illustrates an expansion chamber within a portion of a helical coil;

FIG. 11 illustrates a portion of a catheter having an elongate, thermally-transmissive strip;

FIG. 12 is a sectional view of the catheter of FIG. 3 taken along line 12-12;

FIG. 13 is a sectional view of the catheter of FIG. 3 taken along line 13-13;

FIGS. 14-16 are sectional views of additional catheter embodiments;

FIG. 17 illustrates an inner face of a flexible catheter member;

FIG. 18 depicts yet another embodiment of a catheter in accordance with the invention;

FIG. 19 is a table illustrating cooling performance of a catheter in accordance with the invention;

FIG. 20 is a sectional view of another catheter embodiment;

FIG. 21 is a sectional view of a portion of the catheter of FIG. 20;

FIG. 22 is a detailed view of an area of the catheter portion illustrated in FIG. 21;

FIG. 23 is an illustration of yet another catheter embodiment; and

FIG. 24 depicts still another catheter embodiment.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a schematic illustration of a cryosurgical system in accordance with the invention. The system includes a supply of cryogenic or cooling fluid 10 in communication with the proximal end 12 of a flexible catheter 14. A fluid controller 16 is interposed or in-line between the cryogenic fluid supply 10 and the catheter 14 for regulating the flow of cryogenic fluid into the catheter in response to a controller command. Controller commands can include programmed instructions, sensor signals, and manual user input. For example, the fluid controller 16 can be programmed or configured to increase and decrease the pressure of the fluid by predetermined pressure increments over predetermined time intervals. In another exemplary embodiment, the fluid controller 16 can be responsive to input from a foot pedal 18 to permit flow of the cryogenic fluid into the catheter 14. One or more temperature sensors 20 in electrical communication with the controller 16 can be provided to regulate or terminate the flow of cryogenic fluid into the catheter 14 when a predetermined temperature at a selected point or points on or within the catheter is/are obtained. For example a temperature sensor can be placed at a point proximate the distal end 22 of the catheter and other temperature sensors 20 can be placed at spaced intervals between the distal end of the catheter and another point

that is between the distal end and the proximal end.

The cryogenic fluid can be in a liquid or a gas state. An extremely low temperature can be achieved within the catheter, and more particularly on the surface of the catheter by cooling the fluid to a predetermined temperature prior to its introduction into the catheter, by allowing a liquid state cryogenic fluid to boil or vaporize, or by allowing a gas state cryogenic fluid to expand. Exemplary liquids include chlorodifluoromethane, polydimethylsiloxane, ethyl alcohol, HFC's such as AZ-20 (a 50-50 mixture of difluoromethane & pentafluoroethane sold by Allied Signal), and CFC's such as DuPont's Freon. Exemplary gasses include nitrous oxide, and carbon dioxide.

The catheter 14 includes a flexible member 24 having a thermally-transmissive region 26 and a fluid path through the flexible member to the thermally-transmissive region. A fluid path is also provided from the thermally-transmissive region to a point external to the catheter, such as the proximal end 12. Although described in greater detail below, exemplary fluid paths can be one or more channels defined by the flexible member 24, and/or by one or more additional flexible members that are internal to the first flexible member 24. Also, even though many materials and structures can be thermally conductive or thermally transmissive if chilled to a very low temperature and/or cold soaked, as used herein, a "thermally-transmissive region" is intended to broadly encompass any structure or region of the catheter 14 that readily conducts heat.

For example, a metal structure exposed (directly or indirectly) to the cryogenic fluid path is considered a thermally-transmissive region 26 even if an adjacent polymeric or latex catheter portion also permits heat transfer, but to a much lesser extent than the metal. Thus, the thermally-transmissive region 26 can be viewed as a relative term to compare the heat transfer characteristics of different catheter regions or structures. A thermally-transmissive region or element is not intended to encompass a structure that is excited by RF or other energy source to a point where it begins to radiate heat, for example.

Furthermore, while the thermally-transmissive region 26 can include a single, continuous, and uninterrupted surface or structure, it can also include multiple,

discrete, thermally-transmissive structures that collectively define a thermally-transmissive region that is elongate or linear. Depending on the ability of the cryogenic system, or portions thereof, to handle given thermal loads, the ablation of an elongate tissue path can be performed in a single or multiple cycle process without having to relocate the catheter one or more times or drag it across tissue. Additional details of the thermally-transmissive region 26 and the thermal transfer process are described in greater detail below.

In exemplary embodiments of the invention, the thermally-transmissive region 26 of the catheter 14 is deformable. An exemplary deformation is from a linear configuration to an arcuate configuration and is accomplished using mechanical and/or electrical devices known to those skilled in the art. For example, a wall portion of the flexible member 24 can include a metal braid to make the catheter torqueable for overall catheter steering and placement. Additionally, a cord, wire or cable can be incorporated with, or inserted into, the catheter for deformation of the thermally transmissive region 26.

The cryogenic system of FIG. 1 is better understood with reference to its use in an operative procedure as shown in FIG. 2. Following the determination of a proposed lesion site within a heart muscle 28 for example, the catheter 14 is directed through a blood vessel 30 to a region within the heart, such as an auricle, where the lesion will be made. The thermally-transmissive region 26 is placed proximate to the tissue to be ablated. The thermally-transmissive region of the catheter may be deformed to conform to the curvature of the tissue before, during, or after placement against the tissue. The controller 16 allows or causes cryogenic fluid to flow from the cryogenic fluid supply 10 to the fluid path in the catheter 14 and thence to the thermally-transmissive region 26 to ablate the desired area or to cold map along the same tissue area. In one embodiment (e.g., FIG. 12) a first conduit is concentric within a second conduit and cooling fluid travels to a thermally-transmissive region proximate a closed distal end of the catheter through a first conduit (fluid path) and is exhausted from the catheter through the second conduit (fluid path).

Having described the function of the cryogenic catheter 14 and its use in a

system context, several exemplary embodiments of the thermally-transmissive region 26 of the catheter are now described in greater detail. FIGS. 3, 4, 5, 12-16 and 18 illustrate embodiments of the catheter, or portions thereof, having two or more thermally-transmissive segments in a spaced-apart relationship. Each of the illustrated catheters includes a closed tip 32 that can include a thermally-transmissive material.

Referring specifically to the embodiment depicted in FIG. 3, multiple thermally-transmissive elements 34 are integral with a distal portion of a catheter. Each of the thermally-transmissive elements 34 includes a first side or face 36 (shown in FIGS. 12 and 13) exposed to a cryogenic fluid path and cryogenic fluid (shown by arrows) and a second side or face 38 exposed to points exterior to the catheter. As shown in FIG. 13, the first side 36 and/or second side 38 of any or all of the thermally-transmissive elements 34 can be substantially flush with, recessed below, or protruding from the inner surface 40 and outer surface 42 of a portion of the catheter. The thermally-transmissive elements 34 are separated by flexible portions of material 44 than can range from slightly less thermally-transmissive than the adjacent thermally-transmissive elements to substantially less thermally-transmissive than the adjacent elements. In the illustrated embodiment of FIG. 3, the thermally-transmissive elements 34 are annular, cylindrical elements which are made of gold-plated copper or bronze. Thermocouples 35 can be associated with one or more of the elements 34 and the tip 32. The thermally-transmissive elements 34 can be completely exposed, embedded, or a combination thereof along the full 360° of the catheter's circumference. In certain applications the thermally-transmissive elements traverse or define less than 360° of the catheter's circumference as shown in FIGS. 14-16 and as described below. The longitudinal width of each thermally-transmissive element 34, the spacing between elements, the material thickness, and the material composition are matched with a selected cooling fluid and fluid delivery pressure to produce overlapping cold regions which produce a linear lesion.

The embodiment illustrated in FIG. 4 is substantially identical to the embodiment of FIG. 3, however, at least one of the thermally-transmissive

elements 34 includes a first open end 46 that defines a first plane and a second open end 48 that defines a second plane, wherein the first and second planes intersect to give the annular elements a wedge-like appearance. Such a configuration permits adjacent thermally-transmissive elements 34 to be positioned very closely together, but it can limit the possibilities for deforming the thermally-transmissive region 26, which, in this embodiment, is flexible in the direction indicated by the arrow.

With respect to the embodiments shown in both FIGS. 3 and 4, the thermally-transmissive elements 34 are substantially rigid and are separated and/or joined by a flexible material 44. However, in other embodiments the thermally-transmissive elements 34 are flexible and are interdigitated with either rigid or flexible segments. FIG. 5, for example, illustrates an embodiment of the cryogenic catheter having three thermally-transmissive elements 34 that are flexible. The flexibility is provided by a folded or bellows-like structure 50. In addition to being shapable, a metal bellows can have enough stiffness to retain a selected shape after a deforming or bending step.

Instead of, or in addition to, flexible, thermally-transmissive elements 34 and/or flexible material 44 between elements, the distal tip 32 (or a portion thereof) can be deformable. For example, FIG. 6 illustrates a tip 32 having thermally-transmissive, flexible, bellows 50.

Referring now to FIGS. 7-10, a different approach is shown for providing multiple thermally-transmissive segments in a spaced-apart relationship. FIG. 7 illustrates a catheter embodiment having an elongate, thermally-transmissive region 26 that includes a helical coil 52 at least partially embedded in the flexible member 24. As shown in FIG. 8, at least a first portion 54 of the helical coil 52 is exposed to a fluid path within the flexible member 24 and a second portion 56 of the helical coil is exposed to the exterior of the flexible member. As described above with respect to FIG. 13, the first portion 54 of the coil can be substantially flush with, recessed below, or protruding from an inner surface 58 of the flexible member 24. Similarly, the second portion 56 of the coil 52 can be substantially flush with, recessed below, or protruding from an outer surface 60 of the flexible member 24.

In the embodiment of FIG. 8, the second portion 56 of the coil 52 is exposed along only a portion of the outer circumference of the flexible member 24 to define a longitudinally-elongate, thermally-transmissive region 26. This configuration can be provided by eccentrically mating the helical coil 52 to the catheter so that the longitudinal axis of the coil and the longitudinal axis of the catheter are substantially parallel. The eccentric positioning of the coil 52 provides excellent cooling performance because the surface area available for thermal exchange between the first portion 54 of coil and the cryogenic fluid is greater than the surface area available for thermal exchange between the second portion 56 of the coil and adjacent tissue where cooling power is delivered by each exposed coil portion to provide a linear lesion.

Referring now to FIG. 9, an alternative embodiment is shown wherein a first portion 62 of the coil 52 is exposed around the entire circumference of the flexible member 24, and a second portion 64 is exposed to a fluid path around the inner surface of the flexible member 24. This is achieved by having the longitudinal axis of the helical coil 52 co-axial with the longitudinal axis of the catheter.

In the embodiments illustrated in FIGS. 7-9, the coil 52 is solid. However, in other embodiments the coil can be an elongate, hollow, gas expansion chamber. For example, FIG. 10 illustrates a portion of a helical coil 52 that includes a passage that defines at least a portion of a fluid path through a flexible member of the catheter. The coil 52 defines a first fluid path diameter at a fluid entry point 66 and a second fluid path diameter that is greater than the first fluid path diameter at a gas expansion or boiling location 68. Gas escaping from a fluid exit point 70 can be exhausted through an open central region of the coil and/or another passage through the flexible member 24.

FIG. 11 illustrates an embodiment of the catheter wherein a continuous, elongate, thermally-transmissive strip 72 is longitudinally integrated with a flexible member 24. The strip can include a bellows-like structure. As described above with respect to other embodiments, a first portion of the strip can be substantially flush with, recessed below, or protrude from the outer surface of the flexible member. Similarly, a second portion of the strip can be substantially flush with,

recessed below, or protrude from an inner surface of the flexible member.

Referring now to FIG. 12, an embodiment of the catheter is illustrated having a second or inner flexible member 74 concentric within a first or outer flexible member 24, wherein the second flexible member defines a fluid path to the thermally-transmissive region 26. The inner member 74 can include a single opening 76 at or near the tip 32. Cryogenic fluid is expelled from the opening 76 and returns to the proximal end of the catheter along a fluid path defined by the outer wall of the inner member 74 and the inner wall of the outer member 24. This fluid path configuration is also partially illustrated in FIGS. 8, 9, and 13. Alternatively, as also shown in FIG. 12, the inner member 74 can be provided with multiple openings 78 proximate to and/or aligned with the inner face of one or more thermally-transmissive elements 34 to achieve more uniform cooling across the entire elongate, thermally-transmissive region 26.

Referring now to FIGS. 14-16, sectional views of catheter embodiments are illustrated to show alternative configurations for thermally-transmissive elements. The previously described thermally-transmissive elements 34 are arcuate and form complete and continuous 360 degree structures that traverse the complete circumference of the catheter, notwithstanding being flush with, depressed below, or raised above the outermost surface of the flexible member 24. However, the arcuate elements 34', 34'', and 34''' illustrated in FIGS. 14-16, respectively, traverse less than 360 degrees of the circumference of the first flexible member and do not form complete loops. For example, in FIG. 14, element 34' defines an approximately 270 degree arc. In FIG. 15 the thermally-transmissive element 34'' defines an approximately 180 degree arc; and in FIG. 16, the thermally-transmissive element 34''' defines an approximately 90 degree arc. A catheter can include combinations of element types, such a complete ring or loop element, a 270 degree element and a 180 degree element as desired to define a thermally transmissive region. In addition to the having applicability with respect to rigid thermally-transmissive elements, the bellows-like elements can also be less than 360 degrees.

The less than 360 degree arcuate elements provide unique functional benefits

with respect to thermal transfer and flexibility of the thermally-transmissive region. For example, because the portion of the catheter between the opposing ends of element 34', 34'', 34''' does not include a rigid structure, but rather only the resilient material of flexible member 24, the thermally-transmissive region of the catheter can be more tightly curved (gap between ends inward and element facing outward) than it could with complete 360 degree structures, especially if the elements are relatively long longitudinally.

The inner member 74 can be adapted to direct cooling fluid at only the thermally transmissive element(s) and the shape and/or the number of openings for cooling fluid can be configured differently depending on the length of the arc defined by the thermally-transmissive element(s). For example, FIG. 14 illustrates an embodiment of the inner member having three openings opposing the thermally transmissive element 34'; FIG. 15 illustrates two openings for a smaller arc; and FIG. 16 discloses a single opening for an even smaller arc.

Another advantage to providing one or more thermally-transmissive elements that have a less than 360 degree configuration is that limiting the span of the elements to a desired lesion width, or somewhat greater than a desired lesion width, reduces the thermal load on the system and/or permits colder temperatures to be achieved than with respect to a complete 360 degree structure. Unnecessary and perhaps undesirable cooling does not occur at any other location along the catheter except at an elongate region of predetermined width. A similar effect can also be achieved by providing a non-circular 360 degree element or by eccentrically mounting a circular 360 degree element with respect to the flexible member, wherein a portion of the 360 degree element is embedded within the wall of the flexible member or otherwise insulated from the cryogenic fluid path in a manner similar to that shown in FIG. 8.

Referring now to FIG. 17, a portion of the inner face of an outer flexible member showing thermal transfer pins 80 protruding from the inner face of a thermally-transmissive element 34. The pins permit thermal transfer through the flexible member 24. As with the other features of the invention, the pins are equally suitable for complete 360 degree element structures or less than 360 degree

structures.

Referring now to FIG. 18, yet another embodiment of the catheter is shown wherein rigid metal rings 34a-c are interdigitated with flexible segments 44a-c to define a first flexible member and a thermally-transmissive region approximately one inch in length. A second flexible member is concentric within the first flexible member and has an outlet for cryogenic fluid at its distal end. Thermocouples 82a-c can be associated with one or more of the rings 34a-c.

It has been described above how the thermal loading of a cooling system can be reduced by providing thermally-transmissive elements that span less than 360 degrees. However, the thermal loading can also be reduced by sequentially cooling the tip and rings that comprise the thermally-transmissive region. One way to sequentially cool the tip and rings is to modulate the pressure of the cooling fluid along the fluid path through the flexible member. This modulation can be performed by the fluid controller which can be programmed to increase and decrease the pressure of the fluid by predetermined pressure increments over predetermined time intervals. When the cryogenic fluid is a liquid that provides cooling by changing phase from liquid to gas, the change of pressure alters the physical location along the fluid path where the phase change takes place and concomitantly changes the point of coldest temperature along the thermally-transmissive region. Thus, varying the pressure of the fluid can provide a moving ice-formation "front" along the catheter, enabling the creation of a linear lesion.

Therefore, a method of forming an elongate tissue lesion can include the following steps using any of the above described catheters having an elongate, thermally-transmissive region. In a first step a cryogenic fluid is introduced into the flexible member at a first predetermined pressure. Next, the pressure of the cryogenic fluid is incrementally increased within the flexible member until a second predetermined pressure is achieved. Similarly, the pressure of the cryogenic fluid within the flexible member can be decreased incrementally from the second predetermined pressure to the first predetermined pressure, wherein the steps of incrementally increasing and decreasing the pressure define a thermal cycle. Typically, from one to eight thermal cycles are required to achieve a desired

therapeutic effect. In an exemplary method, about ten increments of about five seconds in duration are selected and pressure is increased by about 20 to 40 pounds per square inch in each increment. Thus, using this method an elongate lesion can be created in less than 20 minutes.

FIG. 19 is a table that illustrates sequential cooling in a catheter as described above having a thermally-transmissive region that includes a tip and three elements or rings. The table illustrates three tests conducted in a still bath at 37°C, using AZ-20 as the cryogenic fluid. Associated with each pressure increment are measured temperatures at the tip, first ring, second ring, and third ring. The shaded region illustrates the sequential movement of a target temperature range (upper -40's to low -50's) in response to a change in pressure. Although values are only provided for three rings, a similar effect and pattern is obtained with more than three rings or elements.

Turning now to FIG. 20, a thermally-transmissive portion of another embodiment of a medical device or structure such as a catheter is illustrated in a sectional view. The structure can include an inner passage or lumen as described above with respect to other embodiments, but which is not shown in this illustration for purposes of clarity. Thus, the illustrated portion is the outer passage or lumen that defines an elongate ablation region. Thermally-transmissive elements 84, such as gold plated copper, are joined to adjacent elements by resilient connecting elements 86, such as a stainless steel springs welded to the ends of the elements 84. A resilient bio-compatible material 88 covers the connecting elements 86 and the interstices between adjacent thermally-transmissive elements. In an exemplary embodiment, the material 88 is vulcanized silicone. It should be noted in the illustration that the surface of the elements 84 is contiguous and co-planar with the material 88 to provide a smooth outer surface.

FIG. 21 illustrates a single thermally-transmissive element 84 having reduced diameter ends 90 and 92. The wider central portion 94 provides an expansion chamber for gas (shown by arrows) exiting an apertured inner passage 96. FIG. 22 shows additional detail of the end 90 of the element 84. The end 90 is textured, such as by providing serrations 98, to provide a good adhesion surface for the

material 88.

Referring now to FIG. 23, a thermally-transmissive portion of yet another embodiment of a flexible cryogenic structure is illustrated in a sectional view. In this embodiment an inner, apertured structure 100 has a flat wire 102 wrapped around it in a spiral manner. Thermally-transmissive segments 104 are disposed upon the wire 102 in a spaced-apart relationship, and a flexible, bio-compatible material 106 fills the interstices between segments 104. A thermocouple 108 can be associated with each segment 104. A wire 109 connects the thermocouple 108 to instrumentation near the proximal end of the structure. The exterior surface of the structure is smooth, and the structure can include 3 to 12 segments 104. In an exemplary embodiment the inner structure 100 is made of PTFE, the material 106 is 33 D Pebax, and the wire 102 is stainless steel or Nitinol. An apertured inner passage (similar to that shown in FIG. 21) is placed within the structure.

FIG. 24 illustrates still another embodiment of a cryogenic cooling structure that includes a surface or wall 110 including a polymer or elastomer that is thin enough to permit thermal transfer. For example, polyamide, PET, or PTFE having a thickness of a typical angioplasty balloon or less (below 0.006 inches) provides acceptable thermal transfer. However, the thinness of the wall 110 allows it to readily collapse or otherwise deform under vacuum or near vacuum conditions applied to evacuate fluid/gas from the structure. Accordingly, the structure is provided with one or more supporting elements 112 such as a spring. The cooling structure is illustrated in association with a catheter 114 having a closed distal tip 116 and mono or bipolar ECG rings 118, 120, 122. The thermally-transmissive region is approximately 30 mm in length and is effective for thermal transfer over its entire circumference. However, as illustrated in FIG. 11, the thermally-transmissive region can be confined to specific region(s) of the device's circumference.

A variety of modifications and variations of the present invention are possible in light of the above teachings. Specifically, although many embodiments are illustrated that are adapted for insertion into the vascular system and are therefore slender and flexible, other embodiments may be thick and rigid, and introduced into

the body directly through incisions or through structures such as trocars. Furthermore, although some of the illustrated devices are particularly well suited for cardiac procedures, the same embodiments and others are equally suited to other organs and/or any body portion that would benefit from the application of thermal energy. Thus, the devices as shown are not to be limited to catheters but should be viewed more broadly as cryogenic structures or portions thereof. It is therefore understood that, within the scope of the appended claims, the present invention may be practiced otherwise than as specifically described hereinabove. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. A cryogenic cooling structure comprising:
an elongate, thermally-transmissive region; and
a cryogenic fluid path through the elongate thermally-transmissive region.

2. The cryogenic cooling structure of claim 1, wherein the thermally-transmissive region includes a plurality of thermally-transmissive elements joined in a spaced-apart relationship by flexible connecting elements.

3. The cryogenic cooling structure of claim 2, wherein the thermally-transmissive elements are substantially cylindrical and arrayed along a common axis.

4. The cryogenic cooling structure of claim 3, wherein each of the thermally-transmissive elements includes a first end, a second end, and an expanded central portion between the first end and the second end.

5. The cryogenic cooling structure of claim 4, wherein an outwardly facing surface of the first and second ends is textured.

6. The cryogenic cooling structure of claim 5, wherein the flexible connecting elements are covered with a bio-compatible material.

7. The cryogenic cooling structure of claim 6, wherein the bio-compatible material defines a surface that is flush with an outermost surface of the thermally-transmissive elements.

8. The cryogenic cooling structure of claim 2, wherein each of the flexible connecting elements includes a spring.

9. The cryogenic cooling structure of claim 1, wherein the elongate, thermally-transmissive region includes a thermally-transmissive flexible material.

10. The cryogenic cooling structure of claim 9, wherein the flexible material is supported by a supporting element.

11. The cryogenic cooling structure of claim 10, wherein the supporting element includes a spring.

12. The cryogenic cooling structure of 9, wherein the thermally-transmissive material comprises a material selected from the group consisting of polyamide, PET, and PTFE.

13. The cryogenic cooling structure of claim 9, wherein the thermally-transmissive material has a thickness less than 0.006 inches.

14. The cryogenic cooling structure of 1, wherein the elongate, thermally-transmissive region includes a plurality of thermally transmissive elements disposed on a helical coil.

15. The cryogenic cooling structure of claim 14, wherein the helical coil includes a flattened metal.

16. The cryogenic cooling structure of claim 14, wherein the helical coil is disposed upon an apertured body.

17. The cryogenic cooling structure of claim 16, wherein the apertured body includes a flexible tube.

18. The cryogenic cooling structure of claim 1, further comprising an ECG ring proximate the thermally-transmissive region.

19. A cryogenic cooling structure comprising:

a plurality of hollow, thermally-transmissive elements joined in a spaced-

apart relationship by flexible connecting elements; and

an apertured tube defining a cryogenic fluid path into each of the hollow, thermally-transmissive elements.

20. A cryogenic cooling structure comprising:

an apertured tube;

a helical coil disposed on the apertured tube;

a plurality of thermally-transmissive elements disposed on the helical coil in a spaced-apart relationship; and

flexible material filling interstices between the spaced-apart thermally-transmissive elements.

21. A cryogenic cooling structure comprising:

an apertured tube;

a helical coil surrounding the apertured tube;

a thermally-transmissive material having a thickness less than 0.006 inches disposed on the helical coil.

22. A cryogenic catheter comprising:

a flexible member having an elongate, thermally-transmissive region; and

a cryogenic fluid path through the flexible member to the thermally-transmissive region.

23. The cryogenic catheter of claim 22, wherein the thermally-transmissive region is deformable.

24. The cryogenic catheter of claim 23, wherein the thermally-transmissive region is deformable from a linear configuration to an arcuate configuration.

25. The cryogenic catheter of claim 22, wherein the flexible member is sealed at one end by a thermally-transmissive, deformable tip element.

26. The cryogenic catheter of claim 22, wherein the elongate, thermally-transmissive region includes a plurality of thermally-transmissive elements having a first side and a second side, wherein at least a portion of the first side is exposed to the cryogenic fluid path and at least a portion of the second side is exposed to points exterior to the flexible member.

27. The cryogenic catheter of claim 26, wherein the flexible member includes an inner surface and an outer surface and wherein the second side of at least one of the thermally-transmissive elements is substantially flush with the outer surface of the flexible member.

28. The cryogenic catheter of claim 26, wherein the flexible member includes an inner surface and an outer surface and wherein the second side of at least one of the thermally-transmissive elements protrudes from the outer surface of the flexible member.

29. The cryogenic catheter of claim 26, wherein the flexible member includes an inner surface and an outer surface and wherein the second side of at least one of the thermally-transmissive elements is recessed below the outer surface of the flexible member.

30. The cryogenic catheter of claim 26, wherein the plurality of thermally-transmissive elements are disposed in a spaced-apart relationship.

31. The cryogenic catheter of claim 30, wherein each of the thermally-transmissive elements are annular.

32. The cryogenic catheter of claim 31, wherein each of the annular, thermally-transmissive elements includes a first open end defining a first plane and a second open end defining a second plane, and wherein the first and second planes intersect.

33. The cryogenic catheter of claim 22, wherein the elongate, thermally-transmissive region includes a helical coil that is at least partially embedded in the flexible member.

34. The cryogenic catheter of claim 33, wherein at least a first portion of the helical coil is exposed to the cryogenic fluid path and a second portion of the helical coil is exposed to points exterior to the flexible member.

35. The cryogenic catheter of claim 33, wherein the flexible member and the helical coil each have a longitudinal axis and wherein the respective longitudinal axes are co-axial.

36. The cryogenic catheter of claim 33, wherein the flexible member and the helical coil each have a longitudinal axis and wherein the respective longitudinal axes are not co-axial.

37. The cryogenic catheter of claim 33, wherein the helical coil includes a passage that defines at least a portion of the cryogenic fluid path through the flexible member.

38. The cryogenic catheter of claim 37, wherein the helical coil includes a cryogenic fluid entry point leading to an expansion location within the helical coil.

39. The cryogenic catheter of claim 26, wherein the thermally-transmissive elements are rigid and are interdigitated with and connected to flexible elements.

40. The cryogenic catheter of claim 26, wherein the thermally-transmissive elements are separated from each other by insulating material.

41. The cryogenic catheter of claim 26, wherein at least one of the thermally-transmissive elements includes a flexible bellows region.

42. The cryogenic catheter of claim 26, wherein the cryogenic fluid path includes a second flexible member concentric with the flexible member.

43. The cryogenic catheter of claim 42, further comprising a thermally-transmissive tip beyond the thermally-transmissive region at the distal end of the flexible member, wherein the second flexible member defines an opening at its distal end, and wherein the distal end of the second flexible member is longitudinally positioned within the flexible member at a point between the thermally-transmissive tip and the thermally-transmissive region.

44. The cryogenic catheter of claim 42, further comprising a thermally-transmissive tip beyond the thermally-transmissive region at the distal end of the flexible member, wherein the second flexible member defines an opening at its distal end, and wherein the distal end of the second flexible member is longitudinally positioned within the flexible member at an intermediate point of the thermally-transmissive region.

45. The cryogenic catheter of claim 42, wherein the second flexible member defines a plurality of openings therethrough proximate the thermally-transmissive region.

46. The cryogenic catheter of claim 45, wherein at least one of the openings through the second flexible member is in direct opposition to the first side of a thermally-transmissive element.

47. The cryogenic catheter of claim 30, wherein each of the thermally-transmissive elements are arcuate.

48. The cryogenic catheter of claim 30, wherein at least one of the thermally-transmissive elements traverses less than 360 degrees of the circumference of the first flexible member.

49. A cryogenic catheter comprising:

a first flexible member having a diameter and flexibility suitable for insertion into a human vascular system, the first flexible member including

an open proximal end,

a closed distal end, and

a deformable, thermally-transmissive region proximate the closed distal end; and

a second flexible member concentric within the first flexible member, the second flexible member including

an open proximal end, and

a distal end that defines a plurality of fluid outlets proximate the deformable, thermally-transmissive region of the first flexible member.

50. A cryogenic system comprising:

a first flexible member including

an open proximal end,

a closed distal end, and

a deformable, thermally-transmissive region proximate the closed distal end;

a second flexible member concentric within the first flexible member, the second flexible member including

an open proximal end, and

a distal end that defines a plurality of fluid outlets proximate the deformable, thermally-transmissive region of the first flexible member;

a cryogenic fluid supply in communication with the open proximal end of the second flexible member; and

a fluid controller interposed between the second flexible member and the cryogenic fluid supply, for regulating the flow of the cryogenic fluid into the second flexible member.

51. The cryogenic system of claim 50, wherein the cryogenic fluid is a gas.

52. The cryogenic system of claim 51, wherein the gas is selected from the group consisting of nitrous oxide and carbon dioxide.

53. The cryogenic system of claim 50, wherein the cryogenic fluid is a liquid.

54. The cryogenic system of claim 53, wherein the liquid is selected from the group consisting of chlorodifluoromethane, polydimethylsiloxane, ethyl alcohol, AZ-20 and freon.

55. The cryogenic system of claim 50, wherein the fluid is introducible into the second flexible member under pressure and wherein the fluid controller is programmable to increase and decrease the pressure of the fluid by predetermined pressure increments over predetermined time intervals.

56. A method of forming an elongate tissue lesion comprising the steps of:

providing a cryogenic catheter comprising a flexible member having an elongate, thermally-transmissive region, and a cryogenic fluid path through the flexible member to the thermally-transmissive region;

introducing a cryogenic fluid into the flexible member at a first predetermined pressure; and

incrementally increasing the pressure of the cryogenic fluid within the flexible member until a second predetermined pressure is achieved.

57. The method of claim 56, further comprising the step of incrementally decreasing the pressure of the cryogenic fluid within the flexible member from the second predetermined pressure to the first predetermined pressure.

58. The method of claim 57, wherein the steps of incrementally increasing and decreasing the pressure comprise a thermal cycle, and further comprising the step of repeating the thermal cycle at least once.

59. The method of claim 58, wherein the cryogenic fluid pressure is increased and decreased in approximately 20 to 40 psi increments in approximately 5 second intervals.

60. A method of forming an elongate tissue lesion comprising the steps of:

providing a cryogenic catheter comprising a flexible member having an elongate, thermally-transmissive region, and a cryogenic fluid path through the flexible member to the thermally-transmissive region; and

sequentially reducing the temperature at different portions of the elongate thermally-transmissive region to a temperature effective for creating a tissue lesion.

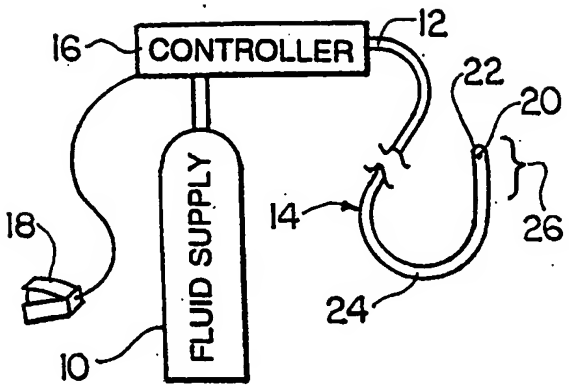


FIG. 1

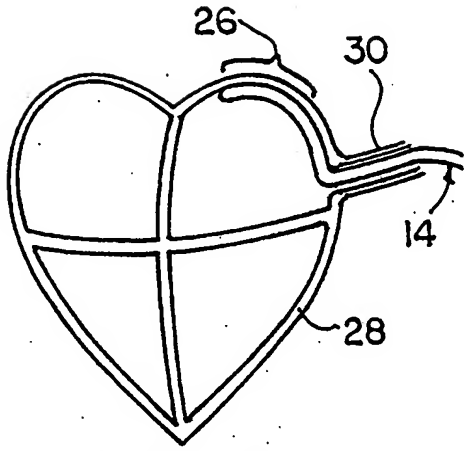


FIG. 2

FIG. 3

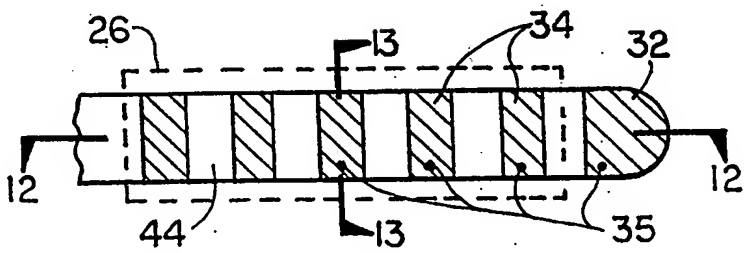


FIG. 4

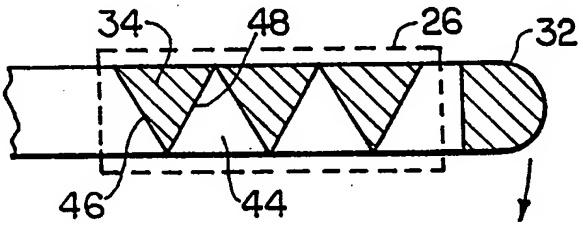


FIG. 5

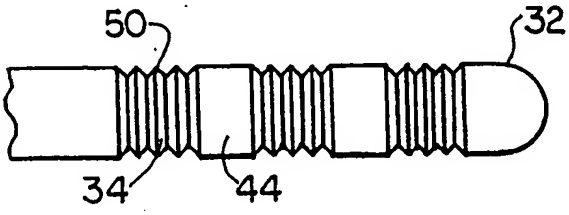
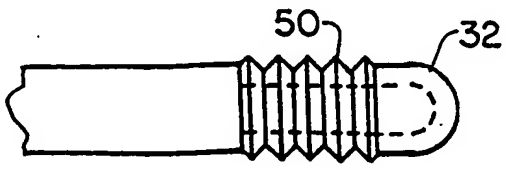


FIG. 6



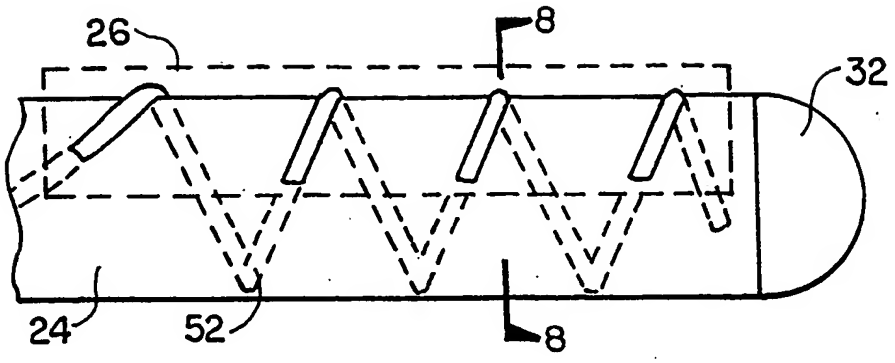


FIG. 7

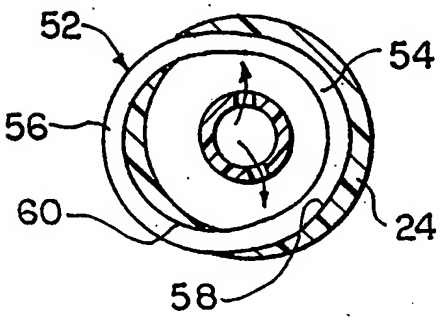


FIG. 8

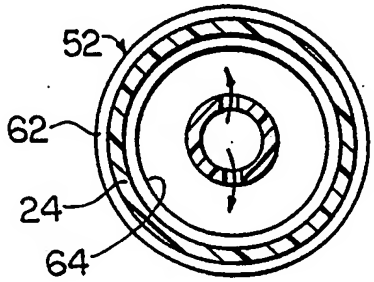


FIG. 9

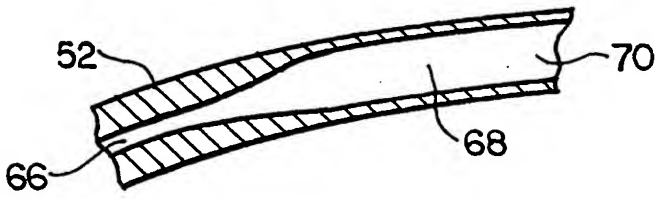


FIG. 10

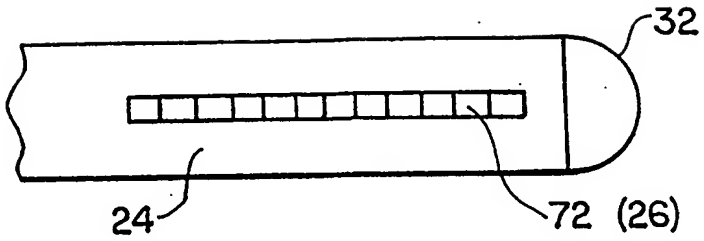


FIG. 11

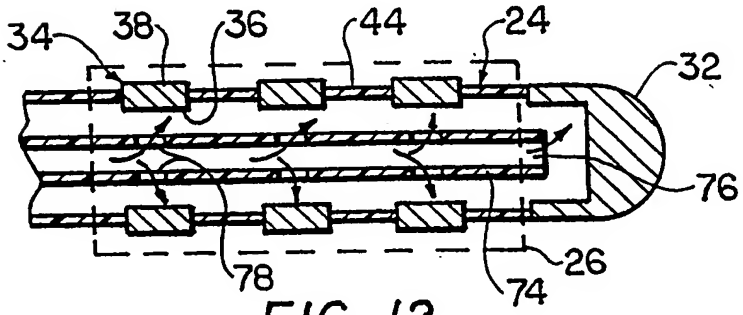


FIG. 12

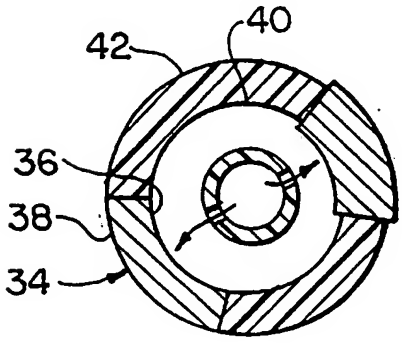


FIG. 13

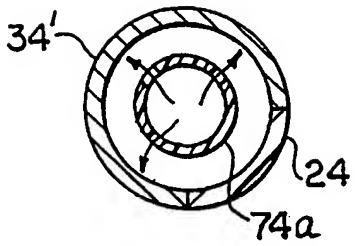


FIG. 14

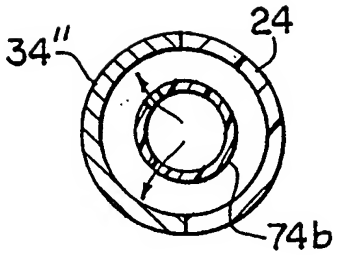


FIG. 15

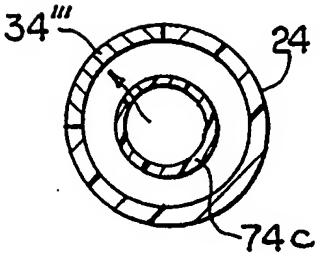


FIG. 16

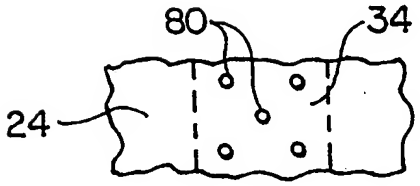


FIG. 17

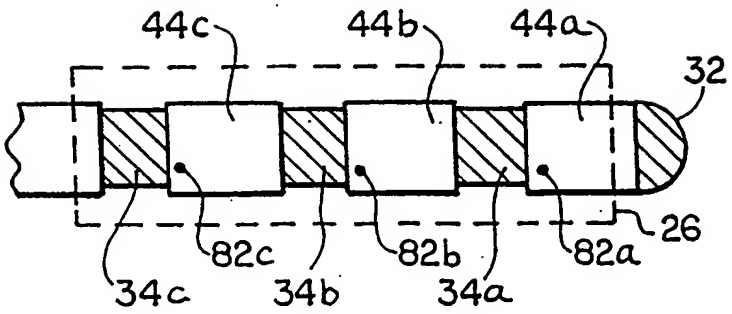


FIG. 18

	PRESS.		TEMPERATURE [°C]		
	[psi]				
		TIP	RING1	RING2	RING3
Test I					
	230	-45	6	16	13
	250	-45	-36	3	1
	270	-43	-43	-19	-20
	290	-40	-47	-23	-22
	310	-40	-47	-32	-25
	330	-39	-47	-38	-27
	350	-39	-47	-47	-31
	370	-40	-47	-48	-45
	390	-39	-47	-48	-49
	410	-36	-46	-47	-49
	430	-36	-46	-48	-49
Test. II					
	235	-50			
	275	-51	-52	-4	6
	300	-44	-50	-53	-2
	325	-43	-51	-52	-24
	350	-43	-50	-51	-33
	375	-42	-49	-50	-52
	400	-40	-49	-50	-53
	425	-39	-48	-49	-51
	449	-37	-47	-48	-50
Test III					
	235	-48	-40	20	25
	275	-48	-42	0	5
	300	-47	-47	-38	-8
	325	-45	-49	-44	-25
	350	-42	-51	-51	-35
	375	-41	-49	-52	-51
	400	-38	-47	-48	-52
	425	-38	-47	-48	-53
	449	-36	-47	-47	-50

FIG. 19

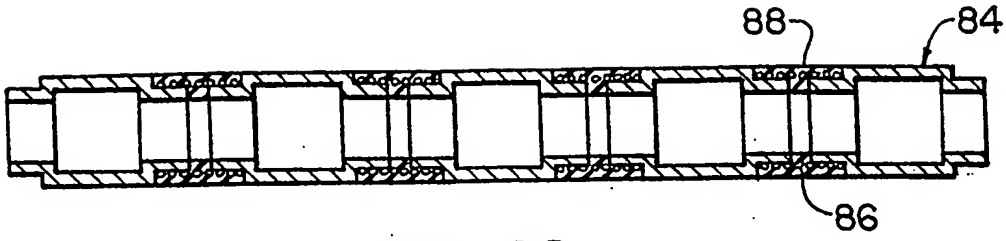


FIG. 20

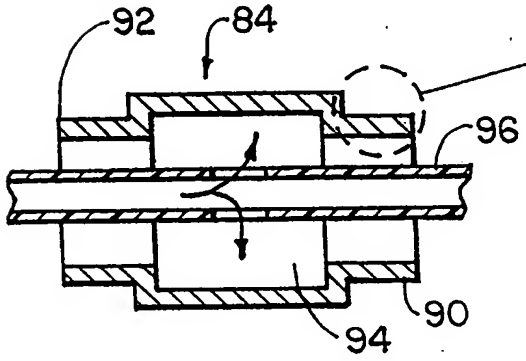


FIG. 21

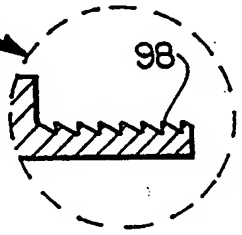


FIG. 22

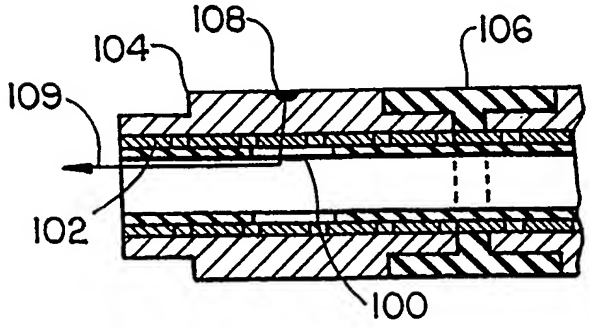


FIG. 23

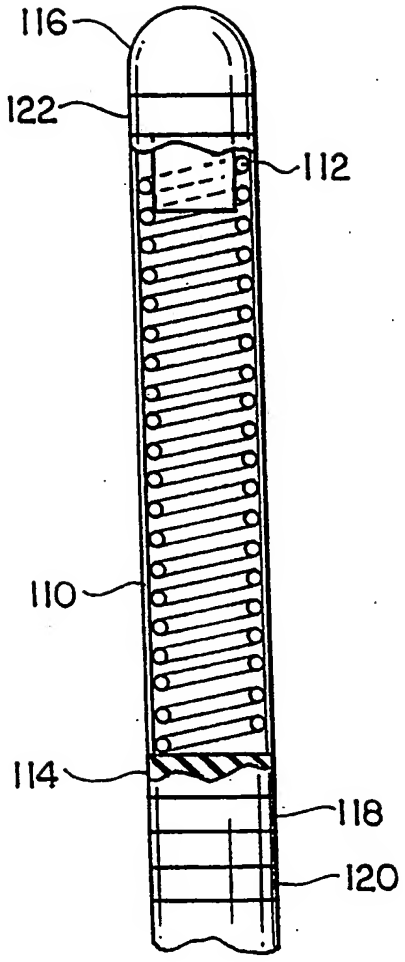


FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03674

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36
US CL :606/20, 22-26; 607/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/20, 22-26; 607/122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,324,286 A (FOWLE) 28 JUNE 1994, ENTIRE DOCUMENT.	1, 22, 33, 35, 37, 38, 56
X,P	US 5,624,392 A (SAAB) 29 APRIL 1997, ENTIRE DOCUMENT.	1, 9, 10, 12, 13, 50-55
Y	US 4,998,916 A (HAMMERSLAG ET AL.) 12 MARCH 1991, ENTIRE DOCUMENT.	10, 11
Y	US 5,517,898 A (FRISBIE ET AL.) 21 MAY 1996, ENTIRE DOCUMENT.	10, 11
Y	US 5,281,213 A (MILDER ET AL.) 25 JANUARY 1994, ENTIRE DOCUMENT.	18, 50-55

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 20 MAY 1998	Date of mailing of the international search report 23 JUN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer ROY GIBSON Telephone No. (703) 305-3520

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03674

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,452,582 A (LONGSWORTH) 26 September 1995, entire document.	1, 19-21, 49, 50
A	US 3,910,277 A (ZIMMER) 07 October 1975, entire document.	1, 19-22, 49, 50